European Medicines Agency

Doc. Ref. EMA/173548/2010
P/38/2010

**EUROPEAN MEDICINES AGENCY DECISION**

**of 31 March 2010**

**on the acceptance of a modification of an agreed Paediatric Investigation Plan for ferumoxytol (EMEA-000373-PIP02-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended**

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

*DISCLAIMER: This Decision does not entitle to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006, as amended.*

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 70
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

**EUROPEAN MEDICINES AGENCY DECISION**

**of 31 March 2010**

**on the acceptance of a modification of an agreed Paediatric Investigation Plan for ferumoxytol (EMEA-000373-PIP02-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council as amended**

THE EUROPEAN MEDICINES AGENCY,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use as amended and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the decision P/248/2009 of the European Medicines Agency on 10 December 2009,

Having regard to the application submitted by AMAG Pharmaceuticals, Inc. on 7 December 2009 under Article 22 of Regulation (EC) No 1901/2006 as amended proposing changes to the agreed Paediatric Investigation Plan,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 19 February 2010, in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended,

Having regard to Article 25 of Regulation (EC) No 1901/2006 as amended,

WHEREAS:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to an agreed Paediatric Investigation Plan,

(2) It is therefore appropriate to adopt a Decision on the acceptance of changes to an agreed Paediatric Investigation Plan.

[1] OJ L 378, 27.12.2006, p.1
[2] OJ L 136, 30.4.2004, p. 1

HAS ADOPTED THIS DECISION:

*Article 1*

Changes to the agreed Paediatric Investigation Plan for ferumoxytol, solution for injection, intravenous use, the details of which are set out in the Opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, are hereby accepted.

*Article 2*

This decision is addressed to AMAG Pharmaceuticals, Inc., 100 Hayden Avenue, 02421 - Lexington, MA, United States.

Done at London, 31 March 2010

For the European Medicines Agency
Thomas Lönngren
Executive Director

(Signature on file)

19 February 2010
EMA/173548/2010

# Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000373-PIP02-09-M01

## Scope of the application

**Active substance(s):**

Ferumoxytol

**Condition(s):**

Iron Deficiency Anaemia

**Pharmaceutical form(s):**

Solution for injection

**Route(s) of administration:**

Intravenous use

**Name/corporate name of the PIP applicant:**

AMAG Pharmaceuticals, Inc.

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended AMAG Pharmaceuticals, Inc. submitted to the European Medicines Agency on 7 December 2009 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/248/2009 of 10 December 2009. The application for modification proposed changes.

The procedure started on 23 December 2009.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu

## Scope of the modification

Some measures and/or timelines of the original opinion have been modified.

## Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to the changes proposed by the applicant regarding the measures and the timelines of the paediatric investigation plan.

   The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex(es) and appendix.

London, London 19 February 2010

On behalf of the Paediatric Committee

Dr Daniel Brasseur, Chairman

(Signature on file)

# Annex I

# The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver

# 1. Condition(s)

Iron Deficiency Anaemia

# 2. Waiver

## *2.1 Condition*

Iron Deficiency Anaemia

The waiver applies to:

- Preterm newborn infants, Term newborn infants (from birth to less than 28 days), Infants and toddlers (from 28 days to less than 6 months),
- for solution for injection / intravenous use,
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

# 3. Paediatric Investigation Plan

## *3.1 Condition to be investigated*

Iron Deficiency Anaemia

### 1.1.1. Indication targeted by the PIP

Treatment of iron deficiency anaemia

### 1.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 6 months to less than 18 years.

### 1.1.3. Pharmaceutical form(s)

Solution for injection, intravenous use, 30mg/mL elemental iron

### 1.1.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | 1 | Age-appropriate vial size. |
| Non-clinical | | Not applicable. |
| Clinical | 4 | Open-label, randomized, active-controlled trial to evaluate safety, efficacy, and pharmacokinetics of ferumoxytol compared with oral iron |

| Area | Number of studies | Description |
|---|---|---|
| | | for the treatment of iron deficiency anaemia in paediatric subjects with dialysis-dependent chronic kidney disease in children from 6 months to less than 18 years.<br><br>Open-label, randomized, active-controlled trial to evaluate safety, efficacy, and pharmacokinetics of ferumoxytol compared with oral iron for the treatment of iron deficiency anaemia in paediatric subjects with nondialysis-dependent chronic kidney disease in children from 6 months to less than 18 years.<br><br>Open-label extension trial to evaluate safety and efficacy of ferumoxytol for the episodic treatment of iron deficiency anaemia in paediatric subjects with chronic kidney disease in children from 6 months to less than 18 years.<br><br>Open-label, randomized, active-controlled trial to evaluate safety, efficacy, and pharmacokinetics of ferumoxytol compared with oral iron for the treatment of iron deficiency anaemia in paediatric subjects in children from 6 months to less than 18 years. |

# 4. Follow-up, completion and deferral of PIP

| **Measures to address long term follow-up of potential safety issues and efficacy in relation to paediatric use:** | **No** |
|---|---|
| Date of completion of the paediatric investigation plan: | By June 2015 |
| Deferral for one or more studies contained in the paediatric investigation plan: | Yes |